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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/045,721 | 10/26/2001 | Naohiro Terada | 5853-207 | 9675 |
| 30448 | 7590 | 02/13/2007 | EXAMINER | |
| AKERMAN SENTERFITT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188 | | | KELLY, ROBERT M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 02/13/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/045,721 | TERADA ET AL. |
| | Examiner | Art Unit |
| | Robert M. Kelly | 1633 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 November 2006.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3,5,6 and 14-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3,5,6 and 14-20 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response and amendments of 11/10/06 are entered.

Claim 8 is cancelled.

Claim 1 is amended.

Claims 1, 3, 5, 6, and 14-20 are presently pending and considered.

Claim Status, Cancelled Claims

In light of the cancellation of Claim 8, all rejections and/or objections to such claim are rendered moot, and therefore, are withdrawn.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

While the previous rejections of Claims 1, 3, 5, 6, and 14-18 are withdrawn in light of the amendments, Claims 1, 3, 5, 6, and 14-20 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record, and as modified by the rejection below. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, from which all the other pending claims are dependent, and therefore encompass, encompasses a method for identifying any drug candidate for promoting tissue-specific differentiation of an embryonic stem cell into any type of cell, with specific method steps.

Applicant only broadly avers that support for this amendment is present in the specification, without further explanation of how the originally-filed specification and claims provide support for such a broad limitation.

The Examiner has reviewed the specification, and found that no explicit support for such a limitation exists, e.g., pp. 1-2, which provide the most explicit support for the claims, does not teach culturing prior to addition of test substances for any specific time period.

Hence, the specification provides no explicit support the limitation. However, page 13 of the specification (paragraph 3), uses implicit disclosure of a specific experiment to show that EB bodies may differentiated from mouse ES cells after two days in hanging drop culture, and then performs 3 additional days in suspension culture, followed by more specific steps to be further differentiated under specific conditions into **hepatocytes** (pp. 13-16). Moreover, Applicant's equivalent to test substances were subsequently added, which are limited to specific factors (p. 16, paragraph 2).

Therefore, the Artisan could not determine that Applicant was in possession of a generic method to identify drug candidates for promoting tissue-specific differentiation of an ES cell, and would further determine Applicant's disclosure to indicate that only hepatocyte lineage cells were possessed.

Response to Argument – new matter

Applicant's argument 11/10/06 has been fully considered but is not found persuasive.

Applicant broadly avers that they have limited the method to the support in Example 2 of the specification (p. 5, paragraph 3).

Such is not persuasive. The steps are much more explicit, and only limited to hepatocyte differentiation, and while enough to overcome the basic argument of the previous rejection, the above more-detailed rejection is now required.

Therefore, the new matter rejection is newly applied.

Claim Rejections - 35 USC § 112 - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

While the previous rejections of Claims 1, 3, 5-6, and 14-20 are withdrawn, Claims 1, 3, 5-6, and 14-20 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the identification of substances which cause EBs to differentiate into the hepatic lineage, does not reasonably provide enablement for a method to screen for substances which cause differentiation into any lineage from EBs, or any tissue specific lineage from ES cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's claims are drawn to identifying compounds that cause ES cells to differentiate into specific tissues, however, the cells are cultured for at least about 5 days prior to adding the test substances.

The specification teaches that the steps of the method are only for forming hepatocytes from EB bodies (EXAMPLE 2). Further, the specification states that the culturing on collagen coated plates further induces differentiation into hepatocytes (p. 16, paragraph 3).

The Art of record fails to demonstrate that other cell types could be formed, and because the collagen at step (C) appears to induce differentiation into hepatocytes, the Artisan could not reasonably predict any other cell type could be formed, as the collagen may overpower any other differentiation pathway.

Hence, the Artisan would have to experiment to determine if any specific obtained compound can actually cause differentiation of an ES cell into any specific cell type.

Such experimentation is considered undue amounting to inventing Applicant's screen for its breadth for Applicant.

Response to Argument – Enablement

Applicant's argument of 11/10/06 has been fully considered but is not found persuasive.

Applicant argues that they have amended the claims to overcome the previous rejection (p. 6).

Such is persuasive, but introduces the above-provided new rejection, necessitated by the amendments.

Claim Rejections – 35 USC § 103 – Liu/Keller

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In light of the amendments, the rejections of Claims 1, 3, and 14-19 under 35 U.S.C. 103(a) as being unpatentable over WIPO document No. WO/10535 to Liu and Leahy, et al. (1999) J. Exp. Zoo., 284: 67-81, are withdrawn.

Specifically, Applicant's specific method steps are now so specific that the Examiner cannot make a rejection under 35 USC 103(a), as to choose those specific conditions, while possible, has no motivation in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In light of the amendments, the rejections of Claims 1, 3, 5, 6, and 14-19 under 35 U.S.C. 103(a) as being unpatentable over WIPO document No. WO/10535 to Liu and Leahy, et al. (1999) J. Exp. Zoo., 284: 67-81, as applied to claim 1 above, and further in view of US Pat No 5,874,301 to Keller, et al., are withdrawn.

Again, the method steps are so specific that it would not be obvious to choose those specific conditions (as ABOVE).

Claim Rejections – 35 USC § 103

In light of the amendments, the rejection of Claim 20, under 35 U.S.C. 103(a) as being unpatentable over Liu/Leahy or Liu/Leahy/Keller as applied to claim 1, above, and further in view of U.S. Patent No. 5,143,854 to Pirrung, is withdrawn.

Again, the method steps are so specific that it would not be obvious to choose those specific conditions (as ABOVE).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

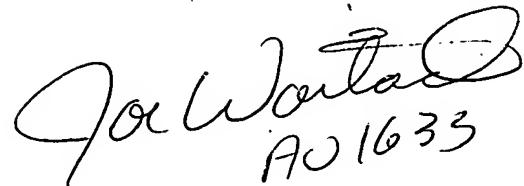
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
Examiner, USPTO, AU 1633
Patents Hoteling Program
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A handwritten signature in black ink, appearing to read "Joe Woitach" above "AU 1633". The signature is fluid and cursive, with "Joe Woitach" being the larger, more prominent part and "AU 1633" being a smaller line below it.